March 10, 2023

TeleEMG, LLC
℅ Barry Ashar
President
Makromed, Inc.
88 Stiles Road
Salem, New Hampshire 03079

Re: K221129
Trade/Device Name: CloudTMS for OCD
Regulation Number: 21 CFR 882.5802
Regulation Name: Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions
Regulatory Class: Class II
Product Code: QCI
Dated: March 28, 2022
Received: April 18, 2022

Dear Barry Ashar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Kang -S

for Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221129

Device Name
CloudTMS for OCD

Indications for Use *(Describe)*
The CloudTMS for OCD is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
for the TeleEMG, LLC
CloudTMS for OCD

(*per 21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*)

1. SUBMITTER/510(K) HOLDER

TeleEMG, LLC
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Los Angeles, CA 90036 USA

Contact Person:
Barry V. Ashar,
Makromed, Inc.
Telephone: (603) 890-3311
Date Prepared: March 28, 2022

2. DEVICE NAME

Proprietary Name:	CloudTMS for OCD
Regulation Name:	Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder
Regulation Number:	21 CFR 882.5802
Classification Name:	Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions
Device Class:	Class II
Product Code:	QCI

3. PREDICATE DEVICES

- Primary Predicate: Tonica Electronik A/S, MagVenture TMS Therapy System for Treatment of OCD, K193006
- Predicate: TeleEMG, LLC, CloudTMS, K160309

4. DEVICE DESCRIPTION

The CloudTMS for OCD is a repetitive transcranial magnetic stimulation (rTMS) system. This computerized medical device produces non-invasive, repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the bilateral dorsomedial prefrontal cortex (DMPFC) for the treatment of Obsessive-Compulsive Disorder (OCD).

The CloudTMS for OCD principle of operation is based on the discharge of high voltage capacitor

(1.8 kV) through stimulation coil; the pulsed magnetic field generated by the discharge current (up to 10 kA) penetrates through neuromuscular tissues nearby to induce electrical currents in cortical neurons. In the OCD treatment protocol, the repetitive transcranial magnetic pulses are applied at a frequency of 20 Hz.

The CloudTMS for OCD consists of the following main components:

- Mobile console
- Cooling unit
- Extra power supply unit
- System software with GUI
- Treatment chair*
- Head support system*
- Coil DCC-03-125-C for both MT and treatment
- K8 Coil fixture
- K3 flexible arm coil positioning system
- Data Management System
- Trolley with casters

(* optional)

5. INTENDED USE

The CloudTMS for OCD system is indicated to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

6. STANDARDS

The CloudTMS for OCD system has been tested and complies with the following standards:

- DIN EN ISO 13485:2016
- ISO 10993-1:2018
- ISO 14971:2019
- IEC 60601-1:2005/(R)2012
- IEC 60601-1-2:2014

7. NON-CLINICAL PERFORMANCE DATA

Electrical safety and electromagnetic compatibility testing demonstrate that the CloudTMS for OCD is compliant with IEC 606101: 2005/(R)2012 and IEC 60601-1-2: 2014.

Only the patient caps in the delivery set of the CloudTMS for OCD have direct contact with the patients. The biocompatibility evaluation demonstrates that the caps meet ISO 10993-1:2018 standard.

Software verification and validation is performed in accordance with the FDA's guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." It demonstrates that the software performs as intended and in accordance with specifications. The potential risks of the CloudTMS for OCD have been identified and evaluated in compliance with ISO14971:2019, and the risks were determined to be acceptable, or have been addressed with risk control measures.

Additionally, non-clinical testing with the CloudTMS for OCD included testing of the magnetic field characteristics of the system, as required by the FDA's guidance document "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems". The magnetic field plots and acoustic output measurements were conducted to demonstrate safety, performance and substantial equivalence to predicate devices.

8. SUBSTANTIAL EQUIVALENCE

The CloudTMS for OCD and the primary predicate device have identical intended use / indication for use and identical treatment parameters and treatment target (see table 8-1 below). Their technological characteristics and performance are very similar so that they can be considered substantially equivalent.

All components of CloudTMS for OCD, except the coil DCC-03-125-C, have been previously cleared by the FDA for MDD indication (Ref: K160309). The new coil is a double cone design whereas the predicate four coils of K160309 were figure-of-eight design. The coils share the same coil materials, cooling mechanism and media, isolation design and functionalities. The new coil is subjected to the same high-voltage tests and leakage current tests as the predicate coils to demonstrate safety.

The new coil DCC-03-125-C share the same Double Cone design of the primary predicate device coil Cool D-B80 (K193006), containing two coils that do not overlap, and allowing for a deeper and broader stimulation of the cortex. To establish substantial equivalence, we have performed comparison of the magnetic field characteristics of the two coils with their respective systems, in accordance with section 4 of the FDA's Class II Special Controls Guidance Document – Repetitive Transcranial Magnetic Stimulation (rTMS) Systems. These include linearity of output levels, magnetic field strength gradients, output waveform and magnetic field spatial distribution.

We have performed a comparative testing of the magnetic field distribution for the DCC-03-125-C coil and compared to that of the primary predicate device. This comparison establishes that the magnetic spatial distribution is substantially equivalent. Both coils are double cone coils with equivalent depth and spread of stimulation of the cortex.

We have performed comparison with the predicate device using well-established simulation models as well as using bench-top experimental measurements. Both methods support technological equivalence between our and the predicate device.

We have provided comparative data on the electrical field distribution produced by both devices, superimposed on T1-weighted MRI coronal, sagittal, and axial slices. These images support the substantial equivalence comparisons determination.

We have not conducted any clinical trials on the subject device of this 510(k) submission. The substantial equivalence is established based on similar technological characteristics. However, we have provided clinical experience safety data on our predicate device (CloudTMS K160309 for MDD) that shares the exact same hardware platform with the subject device. It establishes safe treatments even with the machine output set towards its maximum, with no patient discomfort or adverse events reported.

The basic operational procedures including system setup, patient preparations, motor threshold determination, coil positioning and treatment with predefined treatment stimulation parameters are essentially the same between the CloudTMS for OCD device and the primary predicate device. A detailed comparison of these two devices along with the CloudTMS (Neurosoft TMS for MDD – K160309) device is shown in a tabular form (see table 8-1) below:

Table 8-1. Side-by-Side Comparison of the Proposed Device with Cited Predicate Devices

Area	New Device	Predicate Device K160309	Primary Predicate Device K193006
	CloudTMS with DCC-03-125-C Coil	**CloudTMS** with AFEC-02-100-C Coil	**MagVenture TMS Therapy system – for treatment of OCD** with Cool D-B80 Coil **Tonica Elektronik A/S,Denmark**
Indications for use	The CloudTMS for OCD system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	The Neurosoft TMS is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.	The MagVenture TMS Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).
Recommended Standard Treatment:			
Magnetic Field Intensity	100% of the Leg MT (Leg Motor Threshold)	120% of the MT	100% of the Leg MT (Leg Motor Threshold)
Frequency	20 Hz	10 Hz	20 Hz

Area	New Device	Predicate Device K160309	Primary Predicate Device K193006
	CloudTMS with DCC-03-125-C Coil	**CloudTMS** with AFEC-02-100-C Coil	**MagVenture TMS Therapy system – for treatment of OCD** with Cool D-B80 Coil **Tonica Elektronik A/S,Denmark**
Train duration	2 s	4 s	2 s
Inter-train interval	20 s	11-26 s	20 s
Number of trains	50	75	50
Magnetic Pulses per Session	2000	3000	2000
Treatment Session Duration	18 min	18.75 - 37.0 min	18 min
Sessions/wk	5	5	5
Treatment Schedule	5 daily sessions for 5 weeks, 4 daily sessions for 1 week	5 daily sessions for 6 weeks	5 daily sessions for 5 weeks, 4 daily sessions for 1 week
Area of brain to be stimulated	Dorsomedial Prefrontal Cortex	Frontal Cortex	Dorsomedial Prefrontal Cortex
Waveform	Biphasic sinusoid	Biphasic sinusoid	Biphasic sinusoid
Amplitude in Standard Motor Threshold (SMT) units	0- 2.27 SMT	0- 2.33 SMT	0 - 1.9 SMT
Coils			
Configuration	Double-cone coil	Figure-of-eight coil	Double-cone coil
Core material	Air core	Air core	Air core
Cooling	Liquid cooling	Liquid cooling	Liquid cooling
Coil for MT determination	Used for both MT determination and treatment.	Used for both MT determination and treatment.	Used for both MT determination and treatment.
NUMBER OF TURNS/WING	8	8	7 Upper layer N = 4 turns/wing Lower layer N = 3 turns/wing
NUMBER OF WINGS	2	2	2
NUMBER OF LAYERS	2	2	2

Area	New Device	Predicate Device K160309	Primary Predicate Device K193006
	CloudTMS with DCC-03-125-C Coil	**CloudTMS** with AFEC-02-100-C Coil	**MagVenture TMS Therapy system – for treatment of OCD** with Cool D-B80 Coil **Tonica Elektronik A/S,Denmark**
INNER DIAMETER OF WINDING, mm	96	51	67
OUTER DIAMETER OF WINDING, mm	130	106	95
Design			
	The system consists of: 1. Mobile console 2. System software with GUI 3. Treatment chair* 4. Head support system* 5. Coil positioning system 6. Same Coil for both MT and treatment 7. Coil Fixture 8. Data Management System **optional*	The system consists of: 1. Mobile console 2. System software with GUI 3. Treatment chair* 4. Head support system* 5. Coil positioning system 6. Same Coil for both MT and treatment 7. Coil Fixture 8. Data Management System **optional*	The system consists of: 1. Mobile console 2. System software with GUI 3. Treatment chair* 4. Head support system* 5. Coil positioning system 6. Same Coil for both MT and treatment 7. Coil Fixture 8. Data Management System **optional*
Machine Output Parameters			
The system will automatically be disabled when the coil temperature exceeds:	41 ^oC (106 ^oF)	41 ^oC (106 ^oF)	41 ^oC (106 ^oF)
Frequency range (Hz)	0.1 – 30 (Stand-alone) 0.1 – 100 (with PC)	0.1 – 30 (Stand-alone) 0.1 – 100 (with PC)	0.1-30 or 0.1-100, depending on model
Pulse train duration range (s)	0.5 – 100	0.5 – 100	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 1000 Train duration = Pulses in Train / Rep Rate
Inter-train interval range (s)	0 – 300	0 – 300	1 – 120
Maximum trains per session	4800 = 2400s [max session] / (0.5 s [min train] + 0 sec [min pause])	4800 = 2400s [max session] / (0.5 s [min train] + 0 sec [min pause])	500
Maximum # of pulses per session	72000(Stand-alone)=2400s [max session] *30Hz 240000(with PC)=2400s [max session] *100Hz	72000(Stand-alone)=2400s [max session] *30Hz 240000(with PC)=2400s [max session] *100Hz	500,000 = 1,000 (pulses max per train) x 500 (trains max per session)

Area	New Device	Predicate Device K160309	Primary Predicate Device K193006
	CloudTMS with DCC-03-125-C Coil	**CloudTMS** with AFEC-02-100-C Coil	**MagVenture TMS Therapy system – for treatment of OCD** with Cool D-B80 Coil **Tonica Elektronik A/S,Denmark**
(cumulative exposure)			
Standards			
Electrical safety	Complies with AAMI/ANSI ES 60601-1:2005/(R)2012 IEC 60601-1-2:2014	Complies with AAMI/ANSI ES 60601-1:2005/(R)2012 IEC 60601-1-2	Complies with IEC60601-1 v. 3.1, and IEC60601-1-2.
ISO Standards met	Company complies with DIN EN ISO13485:2016 ISO 10993-1:2018 ISO 14971:2019	Company complies with DIN EN ISO13485:2012 ISO 10993-1:2009 ISO 14971:2007	Company complies with EN ISO 13485:2016.

[1] *see Fig. 1*

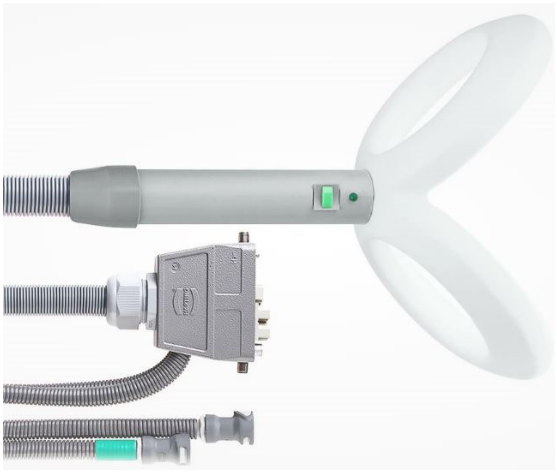

Fig.1 Double Cone Coil for magnetic stimulator

9. CONCLUSION

The CloudTMS for OCD and the predicate devices have identical intended use /indication for use, target population, treatment procedure, treatment position and all recommended standard treatment protocol parameters (intensity, frequency, number of pulses in a train, number of trains in a session, number of treatment sessions).

Both the proposed device and primary predicate device share the same Double Cone coil design. The tested magnetic properties of the CloudTMS for OCD and the primary predicate devices are substantial equivalent for the coils.

The reliability of the positioning method used by the CloudTMS for OCD is based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp, as is the method used in the predicate devices. The method for identifying the correct treatment position in the CloudTMS for OCD is at least as effective as the method employed by the predicate devices.

The CloudTMS for OCD does not introduce any new safety considerations in comparison to the predicate devices. All other identified differences between the two systems are minor and without any known impact on safety or efficacy.

Based on the information and supporting documentation provided in the premarket notification, the CloudTMS for OCD is substantially equivalent to the cited primary predicate device. Testing demonstrates that the CloudTMS for OCD fulfills prospectively defined design and performance specifications.